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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,144	YUM ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 80-84* is/are pending in the application.

4a) Of the above claim(s) ___ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 80-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant has filed supplemental amendment on 3/16/2010. The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 12/24/09. The examiners office action of 3/17/2010 appears to have crossed in the mail.

2. However, in view of the supplemental response filed by applicant on 3/16/2010 after the interview of 2/22/2010,

3. **the office action mailed 3/17/2010** is **vacated**.

4. The supplemental response filed 3/16/2010 cancels claims 2, 4-8, 10-50 and 52-79 and adds claims 80-84 and amends claim 1.

5. Therefore, applicant's request for clarification of the status of the claims in the response of 12/24/2009 is now moot in view of the cancelation of claims 2, 4-8, 10-50 and 52-79 in the supplemental response filed 3/16/2010.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 80 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

8. The recitation that the network former is present at 1-8.6% was not envisioned at the time the application was filed.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 and 80-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al. (US 5,747,058).

12. Tipton discloses a composition comprising drug such as diclofenac (Fig. 12), naproxen (Fig. 14), theophylline (Fig. 15) and codeine (column 7, line 62, the pharmacological agent is not limited), HVLCM such as SAIB (column 3, lines 1-23; column 6, line 39; column 8, lines 50-54; column 10, lines 23-30), Solvents such as ethyl lactate (EL), which is one of the preferred (column 10, lines 23-30), and various additives namely biodegradable polymers, non biodegradable polymers such as CAB, oils and fats such as fatty acid esters, carbohydrates and carbohydrate derivatives (column 9, lines 7, 28, 40, 41, 42) and these additives are present in amount of from about 0.1% to about 20% or from about 1, 2, 5% to about 10% (column 8, lines 60-65). Tipton cautions that oils such as "glycerol, corn oil … super refined peanut oil" are not preferred for use with SAIB (column 10, lines 27-30); all the compositions contemplated by Tipton contain SAIB (see column 5, line 65; column 11, lines 13, 14; at least Figs. 4-17) and when talking about delivery systems names isopropyl myristate (IPM) as preferred fatty acid ester for use with SAIB (column 12, lines 34-37); so that when IPM is used with SAIB, drug and CAB and solvent, the limitation of claim 1 is met and IPM meets the limitation of rheology modifier.

13. When isopropyl myristate (IPM) is the preferred fatty acid ester and used with SAIB, the IPM meets the rheology modifier of claim 1. When the additive is a CAB the requirement for generic and specific network former of claims 1 and 81 are met; the solvent is used from about 5 to about 55%, with from about 10 to about 50% or from about 10 to about 30% preferred (see column 10, lines 31-37) and the narrower range of from about 20 to about 30 percent anticipates the broader range of 20-50% recited in claim 83; Ethanol, DMSO, ethyl lactate (EL), ethyl acetate (EtOac), benzyl alcohol and triacetin are some of the preferred solvents for use with

SAIB (column 10, lines 23-30) and when the solvent is EL or triacetin or DMSO and N-methylpyrrolidone, then claim 84 is met.

14. The diclofenac (Fig. 12), naproxen (Fig. 14), theophylline (Fig. 15) and codeine (column 7, line 62, the pharmacological agent is not limited) meet the generic drug of claim 1 and when at least the substance delivered is codeine, the limitation of opioid in claim 82 is met.

15. SAIB is used in various amounts and combinations, for example Fig. 1, shows data for SAIB from 80%, 90% and 95% SAIB; Fig. 3, shows 90% SAIB; Fig. 4 shows combination of SAIB and CAB, SAIB in amounts of 40%; Fig. 6 shows 50/50, 70/30, 90/10 SAIB/ethyl lactate; and Figs. 7-11 shows other percent amounts of SAIB used in the composition of Tipton. However, Fig 15 and column 5, lines 16-21 described a composition comprising a theophylline drug in combination with SAIB, ETOH, and CAB; the ethanol meets the requirement for solvent in claim 1, CAB at 5% meets the requirement for network former in claims 1, 80 and 81; the various amounts of SAIB anticipates the %amount of SAIB in the range of 30-90% recited in the claims. The composition of Tipton is suitable for topical administration (see claim 13).

16. The recitation in claim 1 that the formulation forms a network within the formulation and an outer surface upon exposure to aqueous environment is a characteristic property of the formulation and the composition of Tipton would be capable of the characteristic property. The recitation that the formulation provides for release of the drug over a prolonged time is also the characteristic of the formulation and further, the formulation of Tipton is a controlled release formulation.

17. Tipton teaches the composition according to claim 1. The difference between Tipton and claim 1 is that while Tipton discloses a number of compositions comprising drugs such as theophylline, codeine, naproxen and diclofenac, SAIB, ethyl acetate as the solvent and CAB that meets the limitation of rheology modifier and teaches that the composition may also contain fatty acid ester additive such as IPM and ethyl oleate, Tipton does not describe one specific composition that comprises SAIB, CAB, solvent and rheology modifier such as IPM and ethyl oleate. The composition of Tipton is suitable for topical administration.

18. However, the disclosure of Tipton suggests the incorporation of fatty acid ester such as IPM in the composition of Tipton. Therefore, one having ordinary skill in the art at the time the invention would have been motivated to include IPM or ethyl oleate in the composition of Tipton containing SAIB, CAB, ethyl lactate solvent since Tipton has suggested the use of fatty acid esters such as ethyl oleate and IPM and the idea of including the IPM or ethyl oleate is suggested by Tipton with the expected goal of obtaining controlled release of active agents such as codeine, diclofenac, theophylline and naproxen for effective enhanced penetration of the drug.

Response to Arguments

19. Applicant indicates that the supplemental response does not replace the response filed 12/22/2009 (received and entered on 12/24/2009). However, it is unclear how that may be so when the claims filed 12/24/2009 have been significantly amended and currently amended claim 1 is the only claim remaining from the claims of 12/24/2009. The examiner will do the best to address both responses as they apply to the currently pending claims.

20. Applicant argues that claims 1 and 80-84 are patentable over Tipton because applicant's view on pages 5 and 6 of the response of 3/16/2009 is that office skipped the general disclosure in columns 7-10 to mouthwash formulation in columns 11 and 12, and then skipped to claim 88 to find individual elements to form the core elements.

21. Response: The examiner disagrees with applicant's premise for the traversal of the rejections of claims 1 and 8-84. The office did not skip columns 7-10 (see at least paragraph 12-14 above). Tipton discloses various compositions comprising SAIB, CAB and solvent in the amounts recited in the claims. Tipton also teaches that the composition can contain oils and fats (see column 9 and 10) and fatty acid esters are included. Three goals of Tipton are to provide a simple system for the delivery of substance, to provide method for the controlled delivery of substances in simple liquid-based system and to provide liquid based delivery system that is easily formulated. To achieve this, Tipton combines HVCLM, solvent, and active agent and additional agents such as biodegradable polymers, non-biodegradable polymers, Oils and fats (discloses in columns 5-10). At least Fig. 15 describes composition that contains SAIB, CAB, EtOH and drug. There is therefore no skipping of any disclosure. In fact, Tipton suggests including the additives named in columns 8-10. The mouthwash formulation discloses in columns 11 and 12 comprises antimicrobial agents, surfactants, co-surfactants, SAIB, water and additives and the additives and solvents. Therefore, taking the teaching of Tipton as a whole reveals the disclosure for a formulation that comprises SAIB, CAB, Solvents and additives such as oils and fatty acid esters. Therefore, it is reasonable to expect that a composition that comprises the same components as recited would also have the same properties since a composition and its properties cannot be separated.

22. On page 7 of the remarks filed 3/16/2010, applicant has stated that the office failed to provide persuasive reasoning to support the conclusion of obviousness.

23. Response: The examiner disagrees because the suggestion to include additives including fatty acid ester is specifically made by Tipton and the artisan apprised by that teaching would include the fatty acid ester such as the IPM or ethyl oleate to promote or enhance the penetration or absorption of the active agent. Tipton teaches or suggests all the components of the claimed formulation.

24. With regards to KSR, the court in the KSR case was clear that a fact finder should not be denied common sense in approaching the prior art as it relates to claimed invention and that "when a structure already known in the prior art is altered by mere substitution of one of the elements for another known in the field, the combination must do more than yield a predictable result." In the present case, the language of the claimed dosage form or dosage delivery device is comprising and open so that the suggestion to add III, which is a variety of optional additives listed as biodegradable polymers, non-biodegradable polymers, oils and fats, carbohydrate and carbohydrate derivatives to I (HVLCM), II (substance to be delivered), IV (Solvent) is a strong suggestion that the composition comprising I (HVLCM), II (substance to be delivered) and IV (Solvent) can contain the additives.

25. Applicant argues on page 8 of the remarks filed 3/16/2010 argues that the characteristics recited in the claims are unexpected and surprising and that something that is unexpected and surprising cannot be predictable and expected.

26. Response: The examiner disagrees with the above argument because applicant has not provided factual showing to show what is unexpected over the prior art. Attorney's arguments

of unexpected results cannot take the place evidence in the record (222 USPQ 191 (Fed. Cir. 1984)).

27. Applicant on pages 9-10 has pointed to paragraphs [0018], [0080], [0082], [0084], [0116]-[0119], [0132]-[0135], [0013], [0014], [0015] as showing that the instant formulation exhibits unexpected and surprising results over currently known formulations.

28. Response: The examiner disagrees in view of the following:-

29. A) [0018] talks about the advantage of reduced extraction of the formulation of drug/HVCLM/CAB/rheology/modifier. But such an advantage is produced by specific composition that is not the same as that claimed in claim 1. Further also, the formulation of Tipton contains SAIB, DRUG, CAP, EL and the suggestion to include fatty acid ester.

30. [0080] describes adjusting the ratio of the ingredients of the formulation and that such optimized formulation provides non-obvious formulation rheology. But in this case, the specification at this paragraph [0080] does not say what the comparison is.

31. [0082] describes kinetic of SAIB/oxycodone. However, claim 1 is not directed SAIB/oxycodone and there are no amounts of the SAIB and oxycodone for the composition for which the kinetics is generated. Also, Tipton describes formulation of SAIB and drug.

32. [0084] is a capsule while claim 1 is not a capsule. Therefore, the scope of the composition in [0084] is different from the scope of claim 1.

33. B) [0116]-[0119] is directed to studying gelcaps of oxycodone, one is commercial product of 80 mg oxycodone and the other is one of SAIB:ethyl lactate:IPM:CAB at a ratio of 65:27:3:5 and at 12 mg/kg, the finding is that the commercial product exhibited large initial burst release while the SAIB containing oxycodone formulation does not present a burst release. The

data presented in paragraphs [0116]-[0119] does not represent the claimed formulation in that the formulation used to obtain the data is a gelcap having SAIB:ethyl lactate:IPM:CAB at a ratio of 65:27:3:5 and at 12 mg/kg which is not the claimed composition (see claim 1). Therefore, the formulation used to collect the data presented in paragraphs [0116]-[0119] is not commensurate in scope with the claimed formulation.

34. C) [0132]-[0135] compares 9 mg oxycodone formulations containing SAIB/CAB/EL and commercial oxycontin formulation. However, the 9 mg oxycodone formulation containing is not the same scope as claim 1; for example, claim 1 is generic to any drug and Tipton teaches various compositions comprising drug/CAB/SAIB/EL and additional component. None of the claims recite oxycodone.

35. D) [0013]-[0015] compares oxycodone formulation with the specific commercial oxycotinin commercial tablets. However, the claims are not directed to oxycodone and the claims have not recited the specific compositions that provide the unexpected results.

36. On the whole, Tipton describes formulation of drug/SAIB/EL/CAB and suggests adding additional ingredients such as fatty acid ester.

37. Therefore the rejection of amended claim 1 and new claims 80-84 over Tipton is proper and maintained.

38. Applicant's arguments filed 12/24/09 have been fully considered but they are not persuasive as they apply to the present rejection and the current claim since applicant has said that the supplemental response does not replace the response filed 12/24/09 the. It is however unclear how applicant can maintain the response filed 12/24/09 when claims 2, 4-8, 10-50 and 52-79 were canceled by the supplemental amendment filed 3/16/2010.

39. In paragraph *(A)* of the remarks, applicant argues that when the claimed invention is considered as a whole, one would fine that the invention provides unexpected beneficial performance characteristics discovered by the applicant by combining "particular set of pharmaceutical excipient" in oral controlled release formulation that provides for long term delivery of potent and potentially dangerous drugs, such as between 1-20 hours or greater, that provides resistance to unwanted extraction of the entire drug dose using solvents such as water and ethanol as shown in the instant application at paragraphs [0045], [0049], [0059], [0062], [0070], [0077]-[0083] of the published application; that provides favorable drug release kinetics during transit through the gastro-intestinal tract when the dosage form is taken as intended thereby decreasing the number of time the drugs must be administered, that provides safe formulations that are less susceptible to abuse, including extraction into water or ethanol, than the prior art tablet or capsule. Applicant thus states that the claimed invention in claim 1 and the claims dependent from claim 1, claims 70, 78 and 79 contain the express combination of 7 basic elements namely: (a) oral dosage form or drug delivery device, (b) containing a formulation that forms a network within the formulation and an outer surface when contacted with an aqueous environment, the formulation includes (c) a drug, (d) HVCLM, (e) network former, (f) rheology modifier, and (g) solvent.

40. Response: The arguments with respect to these claims, claim 1 and claims 70, 78 and 79 are moot. But, the examiner agrees that the claimed formulation comprises (c) a drug, (d) HVCLM, (e) network former, (f) rheology modifier, and (g) solvent and any composition of the prior art that comprises (c) through (g) which is an oral dosage form (a) would have the property of forming a network within the formulation and an outer surface when contacted with an

aqueous environment, which is (b). Thus a capsule or tablet of the prior art that comprises (c) through (g) would also have the characteristic advantage applicant is arguing for because same products must have the same properties. The prior art teaches dosage form in capsule form comprising the specific solvent, ethyl lactate; specific network former, CAB; specific HVLCM, SAIB; specific rheology modifier, IPM; and drug. Thus the composition of Tipton being a capsule is an oral formulation and would have the characteristic of (b) that is the formulation would be capable of forming a network within the formulation and an outer surface when contacted with an aqueous environment. Previous compositions in claims 1, 70, 77, 78 and 79 are disclosed by Tipton as was previously described. However, these claims have been cancelled and as in essence the arguments with respect to these claims are moot.

41. In paragraph *(B)* of the remarks, applicant argues that (i), Tipton does not disclose the expressly recited combinations and the office action at page 5, second paragraph admits that Tipton does not disclose one composition that contains HVLCM, CAB, solvent and rheology modifier; (ii) Tipton does not describe the formulations as having applicant's recited properties and that the office failed to identify a particular composition that would have the recited properties; (iii) Tipton does not disclose the problem that applicant sought to solve.

42. Response: The arguments with respect to claims 1, 61, 70, 78 and 79 are moot in view of the cancellation of these claims. However, (i) On page 5, second paragraph of the office action of 6/25/09, the examiner noted that, "Tipton does not exemplify one composition that has HVLCM, CAB, solvent, and rheology modifier," and it is because there is no exemplification of one formulation that has the HVLCM, CAB, solvent, and rheology modifier, and drug that the rejection was made under 35 USC 103 and not under 35 USC 102. Tipton teaches all the

components of the claimed dosage form so that there is a strong suggestion to combine the disclosed components in one dosage form. Tipton does not exclude any of the disclosed components from being put together in one composition. A prior art is not limited to the examples. Therefore, applicant's arguments with respect to (i) is not persuasive because the prior art is not limited to the examples but the reference as a whole has been considered. (ii) While the examiner agrees that Tipton does not expressly state the properties of the composition, a compositions and their properties cannot be separated. Tipton teaches at least the generic claims directed to broad compositions containing solvent, ethyl lactate; network former, CAB; HVLCM, SAIB; rheology modifier, IPM; and drug, which is the composition claimed in claims 1, 61, 70, 78 and 79 and because same composition must have the same properties, the composition of Tipton must have the recited properties. (iii) Applicant has argues that a problem with drug extraction was solved by the current dosage form and that Tipton does not recognize the problem that needed to be solved. However, the prior art does not have to recognize the problem that needed to be solved; in the present case, Tipton discloses the claimed dosage form and the properties of the composition cannot be separated form the composition so that those properties recognized by applicant to be the problem solved are also attendant in the prior art composition. Furthermore, applicant has not provided a showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04. Also, because, the prior art dosage form would suffer the same fate or has the same characteristic in being the same composition as claims 1, 61, 70, 78 and 79, it flows that

what applicant deems problem that needed to be solved has been solved. Again, the arguments with respect to claims 1, 61, 70, 78 and 79 are moot.

43. In paragraph *(C)* of the remarks, applicant argues the Office has used impermissible hindsight in rejecting the claims because the office action picked ands chose elements form unrelated laundry lists of optional additives that Tipton teaches can be employed with the HVLCM and that the Office has not demonstrated that the cited art teaches or suggests all the claimed limitation; applicant supports this view by citing KSR.

44. Response: The office action did not employ impermissible hindsight in the rejections. Particularly, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, Tipton teaches a capsule (oral delivery system) that comprises drug, HVLCM, solvent and a variety of optional additives and these additives modify the properties of the composition; variety of optional additive is not a teaching that only one additive is used and optional inclusion of additives is a positive teaching that the composition may contain the additive and the composition may not contain the additive. Further, when the additive is a non-biodegradable polymer, CAB, CAP, polyethylene, polyvinyl pyrrolidone, ethylene vinyl acetate, polyethylene glycol are preferred and selecting CAB from a

list of 6 is not a picking and choosing and a list of seven is not a laundry list. With regards to the solvent, ethyl lactate, ethyl acetate, benzyl alcohol, triacetin, N-methylpyrrolidone, propylene carbonate and glycofural are recommended for use with SAIB HVLCM (see, column 10, lines 23-26) and any of the seven solvents can be used and the list of seven is not a laundry list. By the same token, the list of oils and fats that meet the limitation of rheology modifier is not a laundry list. Therefore, just as it was shown in the rejections, the Office demonstrated that Tipton disclosed the claimed dosage form comprising SAIB, CAB, IPM, EL and rheology modifier. The burden shifted to applicant to show that the Tipton disclosed otherwise and applicant has not shown that Tipton does not disclose a composition.

45. MPEP 2143 states "when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." Therefore that the skilled artisan would have had reason to try these methods with the reasonable expectation that at least one would be successful.

46. With regards to KSR, the court in the KSR case was clear that a fact finder should not be denied common sense in approaching the prior art as it relates to claimed invention and that "when a structure already known in the prior art is altered by mere substitution of one of the elements for another known in the field, the combination must do more than yield a predictable result." In the present case, the language of the claimed dosage form or dosage delivery device is comprising and open so that the suggestion to add III, which is a variety of optional additives listed as biodegradable polymers, non-biodegradable polymers, oils and fats, carbohydrate and

carbohydrate derivatives to I (HVLCM), II (substance to be delivered), IV (Solvent) is a strong suggestion that the composition comprising I (HVLCM), II (substance to be delivered) and IV (Solvent) can contain the additives.

47. In paragraph *(D)* of the remarks, applicant argues that the Office failed to show a reasonable expectation of success.

48. Response: The examiner disagrees because if the claimed dosage form is a solution to a problem that applicant has not shown the efforts that have been expended so far, then the disclosed dosage form of Tipton had solved the problem before applicant's invention. If the claimed dosage form comprising HVLCM, CAB, IPM, EL and opioid restricts the abuser from defeating the release of actives within 8, 12, or 24 hours, then the dosage of Tipton comprising, HVLCM, drug, EL, CAB and IPM had achieved the same goal before applicant's invention. Applicant has not demonstrated that the composition of Tipton cannot provide the sustained release pharmacokinetics and applicant has not shown that the claimed dosage capsule is safer than the capsule of Tipton. Paragraphs [0120]-[0129] is not a comparison of the claimed dosage form with the dosage form of Tipton. The in re Dillon case supports the current rejection because, it is said that Federal Circuit case law prior to the Supreme Court's decision in KSR is generally in accord with these statements by the KSR Court. And, the In re Dillon, 919 F.2d 688, 693, 16 USPQ2d 1897, 1902 (Fed. Cir. 1990) (en banc) states ("[I]t is not necessary in order to establish a prima facie case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from the prior art that the claimed compound or composition will

have the same or a similar utility as one newly discovered by applicant"), which supports the case made in the rejections.

49. In paragraph *(E)* of the remarks, applicant argues that the proper consideration of the Graham factual inquiries demonstrates that the office has failed to establish a prima facie case of obviousness.

50. Response: While the supreme court in KSR reiterated the frame work of the Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that obviousness is a question of law based on underlying factual inquiries, the KSR court also stated that "TSM" inquiry is not the only rationale and found that the Federal Circuit erred in four ways namely: "(1) "by holding that courts and patent examiners should look only to the problem the patentee was trying to solve " (Id. at ___, 82 USPQ2d at 1397); (2) by assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem" (Id.); (3) by concluding "that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try'" (Id.); and (4) by overemphasizing "the risk of courts and patent examiners falling prey to hindsight bias" and as a result applying "[r]igid preventative rules that deny fact finders recourse to common sense" (Id.).

51. Therefore, the pending claims are not allowable. The office action had not advocated modifying properties of a composition --- those properties are innate to the composition.

52. No claim is allowed.

53. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

54. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

55. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

56. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618